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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/222,460	12/29/1998	MARC R. HAMMERMAN	A-64236-3-RF	3124

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EXAMINER
GUPTA, ANISH

ART UNIT	PAPER NUMBER
1653	21

DATE MAILED: 08/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/222,460	Applicant(s) HAMMERMAN ET AL.	
	Examiner Anish Gupta	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,7-9,17,20 and 22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4,5,7-9,17,20 and 22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The amendment filed 5-10-02 is acknowledged. The amendment amended claim 1. Claims 1, 4-5, 7-9, 17, 22-24 are pending in this application.

Claim Rejections - 35 USC § 112

1. The rejection of Claims 9 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn.

Claim Rejections - 35 USC § 102

2. The rejection of Claims 1, 4-5 under 35 U.S.C. 102(a) as being anticipated by Sariola et al. is hereby withdrawn.

3. The rejection of claims 1, 4-5 under 35 U.S.C. 102(b) as being anticipated by Liu et al. is hereby withdrawn.

4. The rejection of claims 1 and 4-5 under 35 U.S.C. 102(b) as being anticipated by Rogers et al. Is hereby withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 4-5, 7-9, 17, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerman et al. in view of Liu et al.. for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

Applicants argue that Hammerman does not teach the administration of one or more growth factors at the time of ureteroureterostomy or during or after transplants. Applicants state that the instant claims are drawn to a method wherein the tissue is induced by exposure to growth factors rather than an organ culture. The reference of Lui et al. fails to demonstrate which components of an organ culture actually produce metanephroi enlargement. Applicants state that "it is not uncommon for tissue to grow when it is placed in a nutrient culture for 7 days, irrespective of the presence of IGF-1 in the medium." The reference fails to demonstrate that IGF-1 specifically induces changes in the metanephroi size morphology. Finally, Rogers fails to address the limitation of administration 8 and 2 hours prior to transplantation.

Applicant's arguments filed 7-29-02 have been fully considered but they are not persuasive.

First, no longer is the abstract applied to the rejection, rather the entire reference has been furnished. On page 389 of the reference states that IGF 1 "accelerates and maintains the conversion of induced mesenchyme into the renal epithelium with consequential increase in the size as well as nephron population." Thus, the reference specifically teaches the actions of exogenous IGF-I on metanephric tissue. Further, Applicants attempt to make a distinction between the administration of the culture and the growth factor itself. However, the claims are open ended since they use the terminology "comprising." As a result, so long as the reference teaches a composition containing a growth factor, it sufficiently reads on the claims. Because the reference teaches the role of IGF-1 in tissue enlargement, one would be motivated to use exogenous IGF-I on metanephric tissue. As for the time, one could have optimized favorable times of administration via routine experimentation. As a further note, preincubation of the tissue with the growth factor would be similar to the in-vitro methodology disclosed.

Rejection is maintained.

6. Claims 1, 4-5, 7-9, 17, 20 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammerman et al. in view of Rogers et al for the reasons set forth in the previous office action and the reasons set forth below.

The claims are drawn to the treatment of metanephric tissue using a growth factor containing composition for metanephric development.

Note that the entire Rogers reference has been applied.

Applicants argue that Hammerman does not teach the administration of one or more growth factors at the time of ureteroureterostomy or during or after transplants. Rodgers teach the administration of transforming growth factors endogenously rather than exogenously as recited in Applicant's claims. Moreover, Rogers is limited to in vitro rather than in vivo as claimed. Moreover, Applicants ague that Rogers "fails to demonstrate that TGF-α specifically induces changes in the metanephroi size morphology. Applicants observe that it would not be unusual for metenepheric tissue grown in organ culture for up to six days to increase in size and morphology, irrespective of the presence of TGF-α." Finally, Rogers fails to address the limitation of administration 8 and 2 hours prior to transplantation.

Applicant's arguments filed 7-29-02 have been fully considered but they are not persuasive.

First, no longer is the abstract applied to the rejection, rather the entire reference has been furnished. Rogers acknowledges that their methodology is the endogenous blocking of TGF-α. The reference also states that the exogenous EGF induced enhanced differentiation of thick ascending limb-early distal tubules and collection ducts (see page F538). Further, the reference also states that the EGF and TGF-α interact with a common receptor. The reference concludes that although the disclosed method difference form exogenous administration of EGF, the effects of TGF-α are consistent with the action of exogenous EGF. Therefore, it would have been obvious that TGF-α would be as effective in differentiation of thick ascending limb-early distal tubules and collection ducts as EGF was when added exogenously. Therefore, one would have been motivated to add exogenous TGF-α or at the least EGF. As for the time, one could have optimized favorable times of administration via routine experimentation. As a further note, preincubation of the tissue with the growth factor would be similar to the in-vitro methodology disclosed.

7. The rejection of claims 7-9, 17, 20 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over Woolf et al. in view of Rogers et al.. Is hereby withdrawn.

8. The rejection claims 7-9, 17, 20 and 22-24 under 35 U.S.C. 103(a) as being unpatentable over Woolfe et al. in view of Liu et al. is hereby withdrawn.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta

July 29, 2002

Christopher S. F. Low

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